M 20030

Public Health Service

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

FLA-98-74

September 16, 1998

FACILITY ID NO. 159319

Dr. Allan Pratt
Physician-Director
Obstetrics & Gynecology Associates, P.A.
610 Oak Commons Boulevard
Kissimmee, Florida 34741

Dear Dr. Pratt:

Your facility was inspected on August 21, 1998, by a representative of the State of Florida, on contract to the Food and Drug Administration. This inspection revealed that your facility failed to comply with the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

Level 2 Repeat:

- The interpreting physician, [redacted] M.D., did not meet the continuing experience requirement of having read and interpreted mammograms from an average of 40 patient examinations per 24 months.

The specific deficiency noted above appeared on the List of Observations (Form FDA 483), which was issued to your facility on August 21, 1998. This deficiency is symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of these deficiencies that the inspection identifies and to promptly initiate permanent corrective actions.

If you fail to properly address this deficiency, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

- impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to comply with the standards.

- suspend or revoke a facility's FDA certificate for failure to comply with the standards.

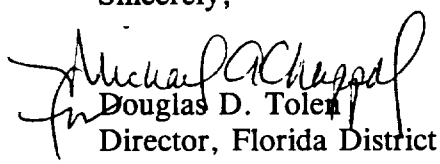
- seek an injunction in Federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude a State from enforcing its own State mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective action(s), therefore, you should consider the more stringent State requirements, if any.

Within fifteen (15) working days after receiving this letter, you should notify FDA in writing of each step your facility is taking to prevent the recurrence of similar violations. If your facility is unable to complete the corrective actions within fifteen (15) working days, you should state the reason for the delay and the time within which the correction will be completed.

Your reply should be directed to Carlos I. Medina, Compliance Officer, U. S. Food and Drug Administration, P. O. Box 592256, Miami, Florida 33159-2256, telephone no. (305) 526-2800, extension 921. Any questions in regard to this letter or how to ensure you are meeting MQSA standards, please contact Mr. Medina.

Sincerely,



Douglas D. Tolen
Director, Florida District

cc: State of Florida